

ABSTRACT OF THE INVENTION

5 A system for designing and monitoring clinical trials includes a main database of information concerning prior clinical trials and resources available to conduct future clinical trials. In part information in the main database is obtained through data links to other
10 databases in the enterprise, *e.g.*, human resources and finance databases. Some of the information in the main database concerns prior clinical trials and is, in part, in the form of a protocol of (a) scheduled visits of a test subject to a treatment site, (b) measurement of prescribed physical attributes of the subject during the visits and (c) administration of at least one prescribed medical product to the subject during the visit to determine over time the subject's response thereto. The protocols of prior clinical trial are stored in the main database in the form of a software template.

15 Users access the main database through their computers which run programs that permit the design and tracking at the user's computer of a clinical trial through access to and use of the software templates. Some users may be served indirectly through subsidiary databases distributed globally. These subsidiary databases contain portions of the data in the main database that relates to the geographical regions where they are located. Data synchronization is maintained by assigning exclusive write capability to rows of the database tables to the main database and subsidiary database, respectively. Then the modified rows are periodically exchanged. The protocol is visually displayed to users as a visit map which
20 shows the visits a subject in the clinical trial is to make to a treatment center and what is to occur at each visit. As visits are made information is added to the system so that the progress of the trial can be monitored. If the protocol is in the form of minor tasks that make up a major task, an event manager system can indicate completion of the major task based on information entered in the system about the completion of the related minor tasks. In addition
25 to visual presentation of the protocol, the system can generate reports and issue orders to other operations, *e.g.*, a clinical supplies group, to facilitate the conduct of the trial.

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